

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

BEVERIDGE & DIAMOND, P.C.
1350 I Street, N.W., Suite 700
Washington, DC 20005

Plaintiff,

v.

Civil Action No. _____

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Office of General Counsel
200 Independence Ave., S.W.
Room 713-F
Washington, DC 20201,

and

NATIONAL INSTITUTES OF HEALTH
9000 Rockville Pike
Bethesda, MD 20892

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

PRELIMINARY STATEMENT

1. Pursuant to the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552, as amended, Plaintiff Beveridge & Diamond, P.C. (“Beveridge & Diamond”) brings this action to compel the disclosure and release of agency records wrongly withheld by Defendants United States Department of Health and Human Services (“HHS”) and its component National Institutes of Health (“NIH”).

2. Beveridge & Diamond filed a FOIA request with NIH on February 15, 2013 (the “Request”), requesting data and information related to a report published by Goldman et al. in

2012 entitled “Genetic Modification of the Association of Paraquat and Parkinson’s Disease” (the “Goldman report”), which was co-authored by scientists from NIH, the U.S. Department of Veterans Affairs, and several non-governmental entities.

3. The Goldman report relied on data related to the Farming and Movement Evaluation (“FAME”) study, a collaborative study involving investigators from the National Institute of Environmental Health Sciences (“NIEHS”) and the National Cancer Institute (“NCI”), both of which are components of NIH, the U.S. Department of Veterans Affairs, and the Parkinson’s Institute and Clinical Center (the “Parkinson’s Institute”). The FAME study, which is highlighted on NIEHS’s website, is co-led by a NIH researcher and features at least four other NIH scientists as investigators. On information and belief, the requested records are held by a third-party contractor, and NIH investigators have access to and control over the records. NIH has produced data and records related to the FAME study in response to a prior FOIA request. Yet, despite NIH’s deep involvement in the FAME study and its past practice, NIH declined to produce any data or records in response to Beveridge & Diamond’s Request.

4. Beveridge & Diamond appealed this denial to the Department of Health and Human Services (“HHS”), but HHS failed to respond to the appeal by the statutory deadline and still has not responded, nearly four months after the deadline, or produced any of the agency records Beveridge & Diamond is lawfully entitled to under FOIA.

5. NIH and HHS have failed to meet their statutory and regulatory obligations under FOIA and HHS’s implementing regulations. Having received no data or response to its appeal to correct this error, Beveridge & Diamond reluctantly has been forced to request that this Court order NIH and HHS to expeditiously release the wrongly withheld data.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action and personal jurisdiction over the parties pursuant to 5 U.S.C. § 552(a)(4)(B). This Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1331.

7. Venue lies in this District under 5 U.S.C. § 552(a)(4)(B).

PARTIES

8. Plaintiff Beveridge & Diamond is a professional corporation incorporated in the District of Columbia with its principal office in Washington, D.C.

9. Defendant HHS is a Department of the Executive Branch of the United States Government, and includes NIH as one of its component entities. HHS is an agency within the meaning of 5 U.S.C. § 552(f), and is in possession or control of the agency records Beveridge & Diamond seeks here.

10. Defendant NIH is a federal public health agency and operating division of HHS. NIH is an agency within the meaning of 5 U.S.C. § 552(f), and is in possession or control of the agency records Beveridge & Diamond seeks here.

FACTS

11. Beveridge & Diamond seeks records and data referenced in and used to prepare the Goldman report, which was prepared in collaboration between scientists primarily from NIEHS and the Parkinson's Institute. *See* Exhibit 1. The requested records and data are agency records subject to FOIA.

12. On February 15, 2013, Beveridge & Diamond submitted a FOIA request by e-mail to NIH requesting seven categories of data and records related to the Goldman report. *See*

Exhibit 2. Beveridge & Diamond requested that the data provided in response to the Request include the same subject IDs that NIH used in a dataset it had produced on September 24, 2012 in response to a prior FOIA request for data related to a 2011 report by Tanner et al. entitled “Rotenone, Paraquat and Parkinson’s Disease” (the “Tanner report”), which also was based on data from the FAME study. This would allow the data for the two related reports to be linked.

13. NIH responded to the Request by letter dated March 18, 2013 (the “Response”). *See* Exhibit 3. The Response stated that NIH searched only the files of the Division of Intramural Research at NIEHS for records responsive to the Request, and the search did not produce any results. Based on this limited search, NIH made a determination that “no records exist which would be responsive to” the Request. NIH also asserted that “the FAME study is being conducted by the Parkinson’s Institute and Clinical Center in Sunnyvale, CA, not by NIEHS or any other component of NIH.” NIH did not produce any of the requested records or data.

14. The requested records and data relate to the FAME study, a study evaluating pesticide use and Parkinson’s disease. The FAME study is a case-control study of Parkinson’s Disease that is nested in the Agricultural Health Study (“AHS”), which is a wide-ranging research project sponsored by NIH (specifically NCI and NIEHS) and the U.S. Environmental Protection Agency (“EPA”). *See* Exhibit 4. Goldman et al. used the FAME data to examine associations among paraquat, specific genetic markers, and Parkinson’s disease.

15. The FAME study is featured on NIEHS’s website as one of the studies in which NIEHS Epidemiology Branch scientists are involved. *See* Exhibit 4. NIEHS maintains its own website about the FAME study. *Id.* The NIEHS website lists published articles that have been

generated using FAME data and published by “the Epidemiology Branch and its collaborators,” including the Goldman report. *Id.*

16. The FAME study is a collaborative study involving investigators from NIEHS, NCI, the Department of Veterans Affairs, and the Parkinson’s Institute. *See* Exhibit 4. The FAME study is “headed” by Dr. Freya Kamel of NIEHS and Dr. Caroline Tanner of the Parkinson’s Institute. *Id.* Two other NIEHS staff scientists – Drs. Jane Hoppin and David Umbach – are “co-principal investigators” in the FAME study, and NIEHS scientist Dr. Dale Sandler and NCI scientist Dr. Aaron Blair are investigators. *Id.* All five of these NIH scientists are listed as co-authors on the Goldman report.

17. The FAME study and the Goldman report were partially sponsored by NIH and NIEHS. The FAME study is nested in the AHS, which is sponsored by NIH, specifically NCI and NIEHS, and EPA. The Goldman report was supported by two grants from NIEHS’s Intramural Research Program, one grant from NCI, and two grants from NIEHS. *See* Exhibit 1.

18. NIH previously produced data related to the FAME study in response to a September 9, 2011 FOIA request by Beveridge & Diamond that sought data related to a 2007 report by Kamel et al. entitled “Pesticide Exposure and Self-reported Parkinson’s Disease in the Agricultural Health Study” (the “Kamel report”) and the Tanner report, both of which were produced based on data from subjects in the FAME study. All of the authors of the Goldman report also were identified as authors of the Tanner report, and all five of the NIH co-authors on the Goldman report were identified as co-authors of the Kamel report.

19. On information and belief, the FAME study data are maintained by Westat, Inc. (“Westat”), a government contractor, for the purpose of records management. On information and belief, the NIH investigators involved in the FAME study have access to and control over

the FAME study data, including the data used in the Goldman report. NIH previously obtained FAME data from Westat to produce in response to Beveridge & Diamond's September 9, 2011 FOIA request regarding the Kamel and Tanner reports.

20. Beveridge & Diamond filed an appeal of the Response with HHS on April 16, 2013 (the "Appeal"). *See* Exhibit 5. In the Appeal, Beveridge & Diamond explained that the requested records and data should be released under FOIA because, *inter alia*, NIH and NIH investigators are significantly involved in the FAME study and the Goldman report; as collaborators in the FAME Study, NIH investigators have access to and control over the FAME study data; and there is no basis under FOIA to distinguish NIH investigators' roles in the Goldman report, for which NIH declined to produce the records, and the Tanner report, for which NIH produced the records.

21. By letter dated April 18, 2013, the HHS Program Support Center acknowledged receipt of the Appeal on April 18, 2013 and assigned it a case number.

22. Under FOIA, HHS had twenty working days – until May 16, 2013 – to respond to Beveridge & Diamond's Appeal. 5 U.S.C. § 552(a)(6)(A)(ii).

23. FOIA provides that, in the event "unusual circumstances" existed, HHS could have extended the May 16, 2013 deadline by a maximum of ten working days by providing "written notice to [Beveridge & Diamond] setting forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched." 5 U.S.C. § 552(a)(6)(B)(i); *see also* 45 C.F.R. § 5.35(c).

24. HHS provided no response by May 16, 2013. HHS did not provide any written notice of an extension and, even if it had, HHS provided no response by May 31, 2013, ten working days after the May 16, 2013 deadline.

25. As of the date of the filing of this Complaint, nearly four months after the statutory deadline for a response to the Appeal, Beveridge & Diamond has not received any written response from HHS or any response indicating whether and when a response might be produced.

26. As of the date of the filing of this Complaint, Beveridge & Diamond has not received any of the FAME records or data it properly requested and is legally entitled to under FOIA.

CLAIM FOR RELIEF

**(Failure to Provide Agency Records in Violation of FOIA and HHS Regulations)
(5 U.S.C. § 552, 45 C.F.R. Part 5)**

27. Paragraphs Nos. 1 through 26 are incorporated here by reference.

28. HHS and NIH violated FOIA and HHS regulations by failing to make properly requested agency records available to Beveridge & Diamond. *See* 5 U.S.C. § 552(a)(3)(A); 45 C.F.R. § 5.35(b)(1).

29. NIH failed to conduct a reasonable and adequate search for the requested agency records, in violation of FOIA, including by, among other things, failing to search agency records maintained by Westat.

30. HHS violated FOIA and HHS regulations by failing to make a determination with respect to Beveridge & Diamond's April 16, 2013 FOIA appeal within twenty working days. *See* 5 U.S.C. § 552(a)(6)(A)(ii); 45 C.F.R. § 5.35(b)(2).

31. Beveridge & Diamond is deemed to have exhausted its administrative remedies as a result of HHS's failure to comply with the applicable time provisions of 5 U.S.C.

§§ 552(a)(6)(A). *See* 5 U.S.C. § 552(a)(6)(C)(i); 45 C.F.R. § 5.35(a).

32. Beveridge & Diamond has a statutory right to the agency records it requested, and, with no legal basis, HHS and NIH failed to adequately search for the requested records, produce even a single responsive record, or respond to Beveridge & Diamond's appeal in a timely manner.

REQUESTED RELIEF

WHEREFORE, Beveridge & Diamond requests that the Court award the following relief:

A. Declare that the failure by HHS and NIH to disclose the records requested by Beveridge & Diamond is unlawful;

B. Order HHS and NIH to disclose the requested agency records to Beveridge & Diamond within ten days of this Court's order compelling production;

C. Award Beveridge & Diamond its costs and reasonable attorney fees incurred in this action; and

D. Grant such other relief as the Court may deem just and proper.

Respectfully submitted,



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